Application
Using compressed air quality monitoring to ensure compressed air quality

Goal
Ensuring product safety and quality by complying with the ISO 8573-1

Sector
Pharmaceutical Manufacturing Industry

Customer
Manufacturer of nucleic acids and proteins

Ensuring Compressed Air Quality Safety and Compliance

In the pharmaceutical manufacturing industry

Client Background

The client is a leading manufacturer specializing in the production of nucleic acids and proteins. They provide comprehensive packaging solutions for pharmaceutical substances to a wide range of partners within the pharmaceutical industry.

With an absolute commitment to product integrity and regulatory compliance, the customer recognizes the importance of maintaining high standards of compressed air quality in their packaging processes.

Challenge

The customer relies on compressed air not only to operate machinery, but also as a critical component of its packaging technology, including blowing air into enclosed chambers during packaging.

To maintain the safety of its pharmaceutical products, the customer must comply with the ISO 8573-1 standard for compressed air quality. Compliance with ISO 8573-1 also helps them achieve the DIN EN ISO 14644-1 standard for clean rooms, ensuring that pharmaceutical production environments meet stringent cleanliness requirements.

However, the customer did not have the necessary equipment to measure compressed air quality to ISO 8573-1.

"Any product contamination of the used compressed air can lead to production stoppages, operational delays and financial loss."

Solution and Implementation

Rectana, a trusted SUTO iTEC partner specializing in precision measurement solutions, worked with the customer to address their compressed air quality safety and compliance needs. They recommended and implemented a comprehensive compressed air quality monitoring solution using SUTO iTEC's instruments:

- **S520 Portable Dew Point Meter:** This portable instrument allows the operators to accurately measure the dew point of compressed air throughout the factory. By monitoring dew point levels, it prevents moisture-related problems that can affect the quality of pharmaceutical packaging.
- **S120 Oil Vapor Monitor:** The S120 permanently detects and quantifies oil vapor levels in compressed air, ensuring compliance with ISO 8573-1 standards. Monitoring oil vapor levels is essential to prevent contamination and maintain product purity.
- **S132 Particle Counter:** The S132 provides accurate measurements of particle contamination in compressed air. By monitoring particle levels, the customer can reduce the risk of contamination and maintain clean room standards.

Results

By integrating SUTO iTEC's monitoring instruments into their operations, the client achieved significant improvements in air quality management:

- **Improved Compliance:** The customer now able to meet ISO 8573-1 standards, ensuring regulatory compliance and adherence to industry best practices. Compliance with ISO 8573-1 also simplifies meeting ISO 14644-1 clean room standards.
- **Improved Product Quality:** By accurately monitoring dew point, oil vapor and particle levels, the customer can maintain optimal conditions for pharmaceutical packaging, ensuring product integrity and purity.
- **Optimized Operations:** The real-time monitoring capabilities of SUTO iTEC instruments enable proactive maintenance and troubleshooting, optimizing operational efficiency and minimizing downtime.

Conclusion

In conclusion, the implementation of SUTO iTEC monitoring instruments has led to improved compliance with ISO standards, enhanced product quality, and optimized operational efficiency for the customer.

By prioritizing compressed air quality monitoring and investing in precision measurement solutions, the client is demonstrating its commitment to excellence and ensuring the safety and quality of its pharmaceutical products.

RECTANA s.r.o.

SUTO

Be smart. **Measure it.**